



MJHH
THE MIAMI JEWISH HOME & HOSPITAL
STUDY ON
HOSPITAL INFECTION PREVENTION

JULY 25, 2008

To better serve MJHH and its patients, this is the first in a series of studies of how MJHH can become the leader in the USA in how to best prevent nosocomial infections in hospitals and other medical and nursing facilities around the country, where secondary hospital infections now cause over 103,000 deaths and several million extended hospital stays a year and costs in the tens of billions.

MJHH is now testing new products and procedures in its goal to reduce deaths and suffering and a huge potential cost factors involved. The first group of tests was for a new class of probiotic products that have had major success in Europe.



MJHH - THE MIAMI JEWISH HOME & HOSPITAL REPORT ON TESTING PROBIOTICS TO REDUCE NOSOCOMIAL INFECTIONS

By Neil Caseiro, Director Environmental Services & Special Projects

THE PROBLEM

Nosocomial infections cause substantial morbidity & mortality, prolonging hospital stays and increase direct patient-care costs. The situation is rapidly growing even more disastrous because of the continued growing resistance of pathogens due to overuse of antibiotics and disinfectants.

To further exacerbate the problem, increasingly, hospital infections cannot be cured anymore with commonly-used antibiotics. For a medical complex of excellence, like MJHH, which sets the standards for cleanliness and procedures, serving as a model for the rest of the United States and the world, there are constant additional challenges to maintain preventative measures since MJHH serves a more elderly population than most medical centers.

ESSENTIAL FACTS:

- **Infections contracted in hospitals are the fourth largest killer in America.** Every year, two million patients contract hospital infections, and an estimated 103,000 die as a result. This is as many deaths as from automobile accidents, AIDS, and breast cancer combined.
- **Hospital infections add some \$30.5 billion a year to our country's hospital costs.** However, though patients, insurers and taxpayers pay part of that cost, hospitals have to absorb much of the costs. As a result, infections seriously erode hospital operating incomes and for a not-for-profit organization like MJHH that serves the community, the continued best possible practices for preventing infections are critical to continue assuring the best possible use of resources for patient care. Of course, commercial hospitals have the same concerns, as preventing nosocomial infections can be the difference between profit and loss.
- **Terrorism & Natural Disasters:** It should be noted that better infection prevention in hospitals is essential to prepare for possible mass events like avian flu or bioterrorism. In any disaster hitting the U.S., the death toll would largely depend on what American hospitals do when the first infected patients are admitted. If hospitals have effective infection controls in place, they can better prevent epidemics like the bird flu from infecting other patients. If not, infections can burn through hospitals and nursing facilities. Today, most hospitals and other medical facilities are woefully under prepared, as most have failed to stop the spread of ordinary infections. MJHH strives to set the standards for other facilities and infection control is one of the first priorities.

- **The Major Problem:** It should be noted that insufficient hygiene and procedures are the key factors contributing to Nosocomial infections. Part of the solution to this reality is the reason for this study and report, which may make up in part for human error.

THE MJHH HOSPITAL AND CARE FACILITIES

Established in 1945, located at 5200 NE 2nd Avenue, Miami, FL 33137, MJHH offers the most comprehensive continuum of care for senior citizens in the Southeast United States. Located on 28 acres and in eight (8) building in the center of Miami, MJHH has a total of 740 beds along with an additional campus. The hospital provides the following key services: Subacute Care, Rehabilitation Therapy (in-patient and out-patient services), Skilled Nursing Care, Pulmonary Care, Long-Term Services and MJHH's satellite Douglas Gardens Medical Center provides 14 medical sub-specialties.

MJHH's departments include:

Cardiology	Dermatology
Endocrinology	Gastroenterology
Nephrology	Neurology
Ophthalmology	Optometry
Orthopedics/Rehab. Evaluations	Pacemaker Clinic
Psychiatry	Pulmonary
Rheumatology	Urology/Incontinence Clinic
Wound Care Clinic	Gastro-Intestinal I series
Modified BA swallow (video fluoroscopy)	Psychological Testing



PROJECT INTRODUCTION

Because we continue to see the data from around the country a large rise in nosocomial infections of patients due to greater numbers of highly resistant microbiological organisms resulting from the overuse of antibiotics and disinfectants, our Environmental Services Department at MJHH is constantly searching for better ways to protect against these realities.

Therefore, when one of MJHH's external benefactors called the hospital to suggest we look at a new probiotic solution for preventing nosocomial infections, we were willing to review the data to see if the solution merited further study. The problem is that there are so many claims these days for new products to reduce secondary infections that sorting through them requires diligence and a factor always in short supply, time, to sort through them. However, we set up an initial meeting with the providers of the solution.

EVALUATION MEETING

As the Director Environmental Services, I am responsible for all of the cleaning and servicing of all the buildings on the main 28 acre hospital and nursing home site. Therefore, I chaired the evaluation meeting in April of 2008 for the hospital in my department's offices. Also representing the hospital at the meeting was Pablo Mora, the Infectious Control Nurse for our facilities.

The proposed solution provided was the "Chrisal PIP Probiotic Healthcare solutions". The key claims presented to the hospital for this new range of probiotics cleaning

products was that the reports from other medical institutions and a university show that the Chrisal PIP (Probiotics-In-Progress) products appeared to provide a number of benefits, however the six key prime points of interest presented were:

- 1) That the PIP products, as part of their cleaning process, actually changes and controls the environment on surfaces cleaned that result in the elimination or great reduction of harmful bacteria and therefore, of nosocomial infections as well. This was stressed as a factor that made the products a major cost savings one rather than an expense item. Further, that the PIP products should be thought of as insurance.
- 2) That the PIP products actually continued to work and provide protection for up to three days. After 72 hours, their protective ability became reduced. However, since the major problem with disinfectants is that they normally stop working in minutes as soon as they are dry, if the Chrisal PIP claims were valid, that would, of course, be of major interest to our or any medical facility.
- 3) In line with the claims above (2), the cleaning action of the product also was claimed to be ongoing and lasting at least some 72 hours after each application. That in addition to the immediately cleaning provided, areas cleaned would continue to have cleaning action, such as grout between tiles rejuvenated to their original color/state.
- 4) Far more important is the claim that one of the key functions of the Chrisal PIP products is that they will eliminate bio-films (and any resulting bio-mats) and once eliminated, PIP will prevent their re-growth. As bio-films are what protects pathogens, traps dirt along with supporting viruses and prevents disinfectants from working properly, this claim was also of great interest.

Note that we were advised that PIP stood for Probiotics-In-Progress and that, though the Chrisal products produced immediate results, their overall affect was “progressive” and that they built up control over the first few weeks of use and then maintained this control thereafter.

- 5) Another claim was that the PIP product could be used constantly and effectively without any damage to skin and that gloves were never needed for protection from the product, like with many standard products. Also there was no odor or dangerous fumes to be concerned about.
- 6) The last factor that stood out was the claim that using Chrisal PIP reduced workloads and storage requirements

The representatives of Chrisal at the meeting were Howard Zalkin from the Miami Area and Kim Heemskerk, a representative of the main Chrisal plant from Belgium where the original products and patents were formulated.

DECISION FACTORS: Though the medical and scientific data presented for the Chrisal PIP solutions was impressive, we were, naturally, extremely skeptical without an internal test and the first question was if these products were worth the time and resources for proper testing. Therefore, we went through the following steps:

MICROBIOLOGICAL VIEWPOINT: From a microbiological viewpoint, our Infectious Control department representative, Pablo Mora, went through the actual mechanism of how the products worked, and determined that "if" the products worked as stated, then they were far ahead of the curve of current solutions and not only cleaned, but actually controlled the environment.

EASE OF USE QUESTION: An additional factor was that the products were extremely simple to use and required no special steps for their testing or in their use. One simply substituted the Chrisal PIP Probiotic cleaners for the regular ones currently used.

REDUCTION OF NUMBERS OF PRODUCTS REQUIRED: One other interesting factor of real interest, if proved out, was the fact that the Hospital currently uses some 17 different cleaning products to be able to accomplish the required results and the Chrisal PIP line, due to the presented power of the products, would replace most of these current 17 products with only three (3) products that covers almost all areas of current cleaning and disinfecting. If so, this would also reduce overhead and space costs as well as eliminate additional demand on staff.

DECISION: Due to these factors, we decided to proceed with the testing.

TEST STRUCTURE AND MANAGEMENT

As the Director Environmental Services, I took charge of directly supervising all the phases of the testing of the Chrisal products used by the staff. To prevent wasting time on mishaps and due to the potential importance of the testing, I personally was present for the sampling and cultures of all the areas being tested for both the pre-use testing and of all the weekly testing thereafter.

To avoid any question of outside interference, since the Chrisal team requested to be present during testing and to take duplicate samples at the same times MJHH did for comparison, I asked them not to bring in any additional staff until the testing was over and to schedule all visits with me to limit access and for proper control.

In addition, I also controlled all the sampling as well as the storing of all the culture media from the tests. To do this, I supervised the taking of cultures and then, to maintain complete control, photographed and stored the resulting plates in the freezer section in the unit in my office to control access. To assure a solid review of the testing and usage results of the Chrisal products, I have requested the input from a number of staff from different departments as part of the reviewing team for the Hospital.

TEST TARGET RESULTS

As there was a great deal of natural skepticism about the projected results from the Chrisal materials, as though highly desired, they were hard to accept. The premise was that by simply changing to cleaning with the Chrisal PIP probiotic line of products, a already clean hospital facility would further lower the risk of harmful bacteria in the hospital "over existing hospital products" by at least 50%, but actually by 80% in most

cases to well over 90% in others. After reviewing all the data presented, we picked a number of initial areas to test the Chrisal products including patient rooms.

PRE-TESTING PREPARATIONS

In preparation for the testing of Chrisal PIP, I wanted the testing to be as stringent as possible. Therefore, I sent my team to provide a special cleaning of the areas in which Chrisal would be tested, with the instructions to be extra thorough and pay attention to every inch of each area.

We felt that this was needed to properly provide a valid test of Chrisal. It was felt that special attention and a thorough cleaning needed to be done by the Hospital's cleaning staff of all the test areas using the Hospital's existing acceptable cleaning products. This would then provide a realistic base line for the testing.

PRE-TESTING CULTURES

After extensive cleaning and prior to using the Chrisal products, we took cultures from a number of sites in the testing areas. Each site where cultures were taken were numbered and noted so as to properly repeat testing in each same exact area each week. For the cultures, 3M Test Kits were used with the 3M Quick Swabs for best accuracy. All testing was done in the presence of all the parties; however complete control of the test kits done for the hospital was retained by me.

Once the tests were incubated for the required time period, I then froze the samples in the freezer compartment of the refrigerator unit directly in my office in order to assure accuracy and the controlling of the entire testing done. Further, the samples were numbered by us without telling Chrisal what slides went with which areas.

TEST RESULTS – FIRST PHASE

It was also decided that the hospital staff would handle all the cleaning for the tests. After the pre-testing cultures were taken, the Hospital staff was trained in the simple procedures of using the Chrisal PIP Probiotic Products by the Chrisal representatives and then our staff started cleaning as they always did, with the exception of only using Chrisal products in the test areas set aside for this program. Note that the only requirement requested by Chrisal was that no other products be used in the test areas.

WEEKLY CULTURING SCHEDULE

It was decided that full culturing would be done once each week of all the areas being tested as the best way to judge progress.

PRE-CHRISAL TESTING CULTURE MEDIA TESTS RESULTS

The results of the cultures taken after cleaning with the hospital's normal products before the use of Chrisal was initiated were a surprise. MJHH is one of the cleanest facilities in the USA and its staff extremely well trained. What the pre-testing cultures showed (and what turned out to be the norm in all hospitals, clinics, restaurants tested) is that even in the best of facilities with the most stringent of cleaning programs, using

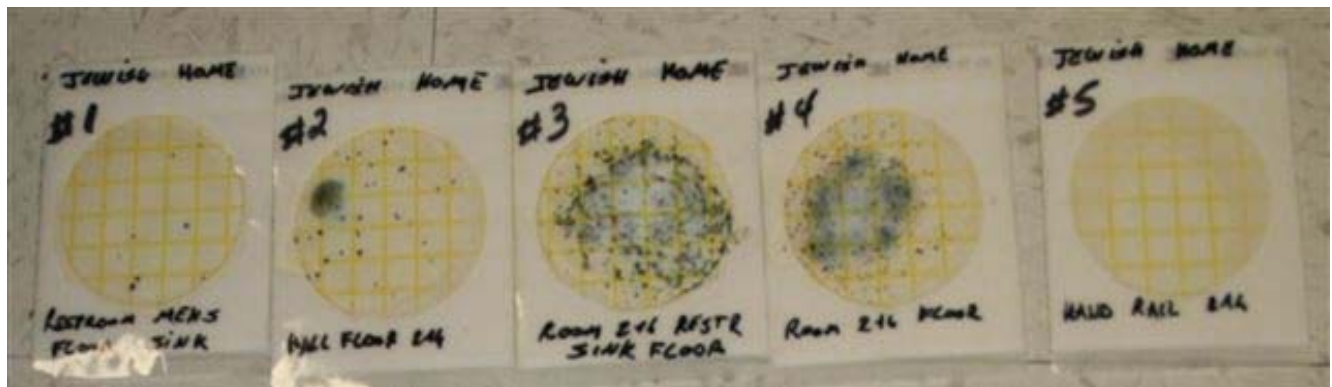
the most powerful of disinfectants, facilities, true protection against pathogens is far more difficult than existing programs can normally expect to achieve.

It was seen was that following infectious control procedures is critical because no matter how well an area is cleaned with normal disinfectants, it can be contaminated minutes later.

In the first round of testing, the locations selected including patient rooms, a patient sink, patient bathroom floor, between the beds, the hall hand railing between patient rooms, the tile outside patient rooms, the men's bathroom and toilet floor, as well as the department's door handle and work table.

For these first rounds of tests, the 3M culture media kits used were to detect staphylococcus. E-coli, Listeria, salmonella and a number of other tests were slated for round two if the PIP products passed the first round. These are especially important for the food processing and serving areas.

OVERALL PRE-CHRISAL TESTING: The following test cultures were some of the ones taken in the test areas shortly after the special cleaning by staff using standard hospital cleaning materials:



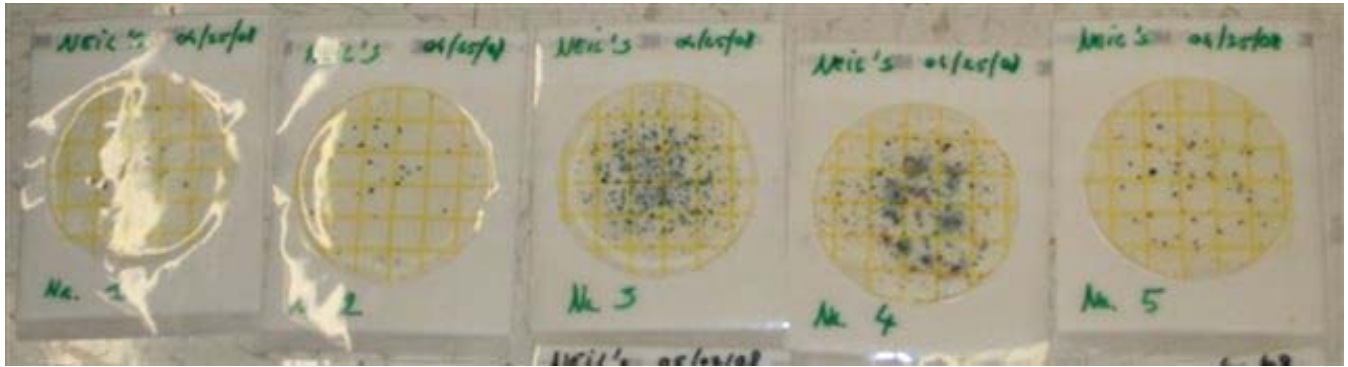
Results using pre-test standard hospital cleaning products

POST-CHRISAL USE CULTURE MEDIA TESTS RESULTS WEEK-1

The following are the results below of the testing of the exact same areas as previously tested in the pre-Christal use testing.

These first post-Christal cultures were taken exactly one week after the start of the use of Christal PIP in the test areas.

Note significant improvement in three of the badly contaminated areas. However, one contamination rise was noted in slide 5. Since this was an oddity with most of the test, it is not known if a simple mix up in products use or simply part of the normal fluctuations in line with the “progressive” nature of the product advised us that builds up over the first few weeks of use.



Post-Chrisal Use Results – Week -1

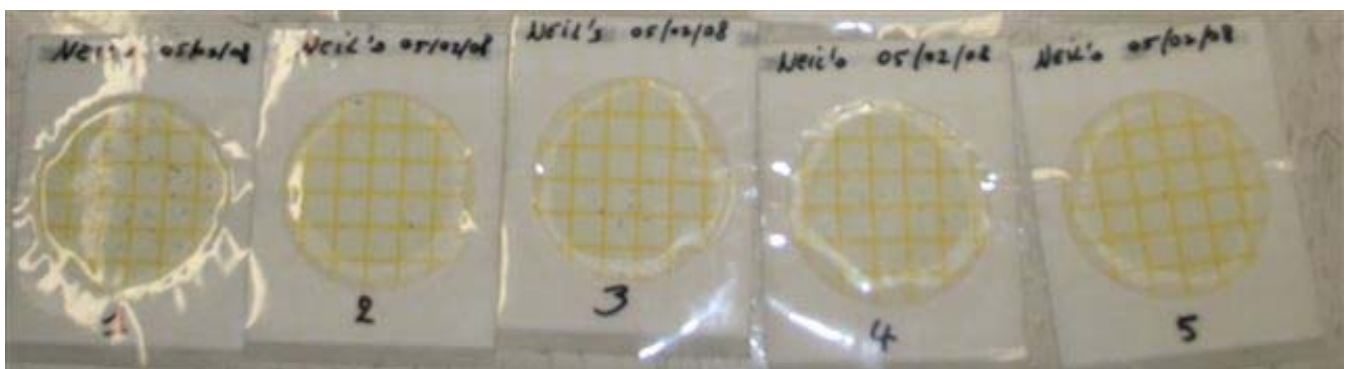
ONGOING POST-CHRISAL CULTURE MEDIA TESTS RESULTS WEEK-2

The following are the results of the week-2 testing of the exact same areas as previously tested in both the pre-Chrisal use testing and then repeated the first week after the start of the use of Chrisal PIP in the test areas.

As can be seen, by the end of the second week of Chrisal PIP usage, all of the areas were almost totally devoid of any harmful bacteria.

During the first week, there was a spike in test area number 5, but it is not known if other products were used in the area or what the reason was for the small spike that day, or if this is just the natural progression stated by Chrisal at the beginning of the testing that the PIP products are progressive and take a week or two to take hold and control the areas to which they were applied.

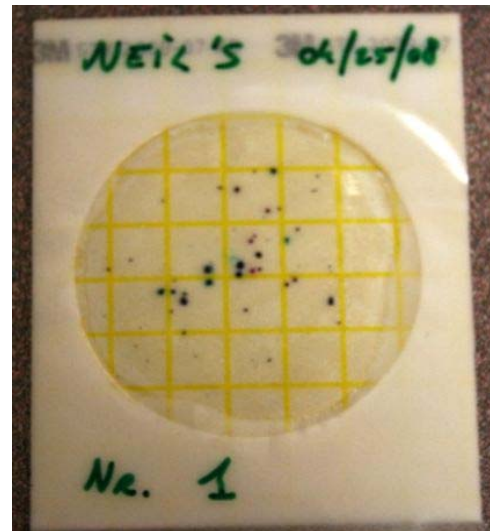
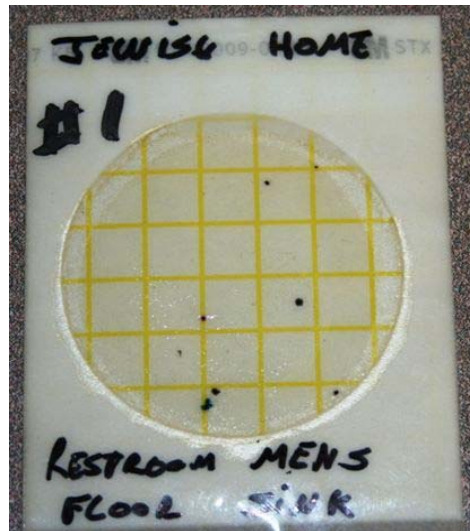
However, overall in all the areas tested using Chrisal PIP products, within two weeks of starting, the PIP products appeared to take firm hold of the areas tested and produced cleaner and safer areas.



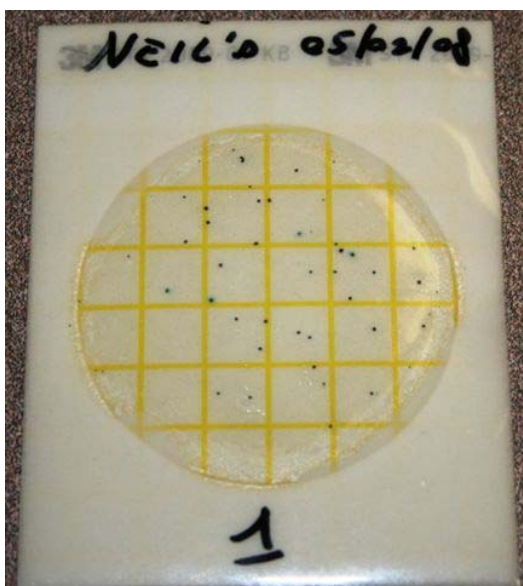
Post-Chrisal Use Results – Week - 2

ANALYSIS OF ANY PROBLEM AREAS

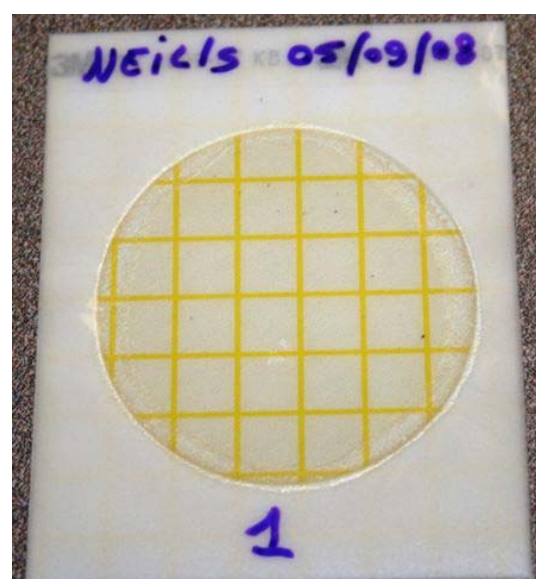
Though it can be seen that the Chrisal PIP applications made rapid and major progress for heavily contaminated areas in just the first week, there were several spots where there were small spikes that did not follow the general trend. It is not known why or if it was due to mixing of products, but it would be interesting to do extensive long term testing of many areas where strict controls of the products used in each test area is done to see what might cause this. However, by the second week of Chrisal use, it was seen that the product did take hold. Here are the areas that required a second week. **Below, for area one, the left slide is pre-testing** and the **right slide is after the first week of testing**, which did not show control of the area, which may or may not be due to outside factors:



However, in the **second (2nd) week of testing**, the Chrisal PIP appeared to take hold of the area and then in the **third (3rd) week**, the control of the area appears complete and all testing from that point on remained clear of contamination.



Week-2



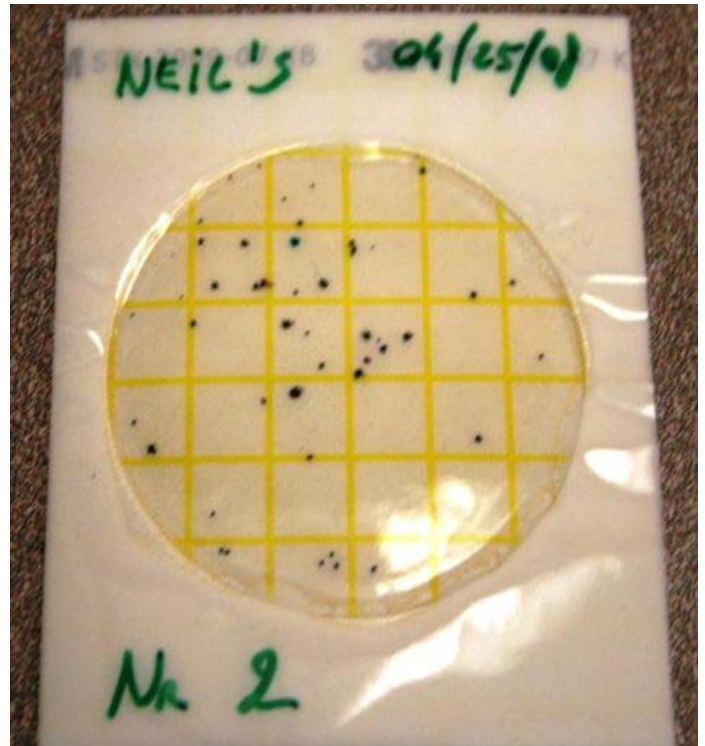
Week-3

Progress of Chrisal PIP usage testing in a more heavily contaminated area:

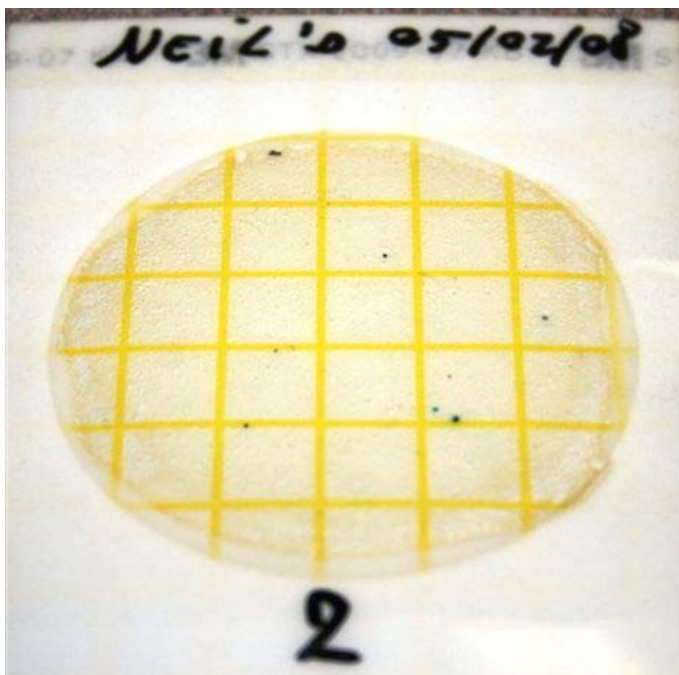
Culture testing before Chrisal use



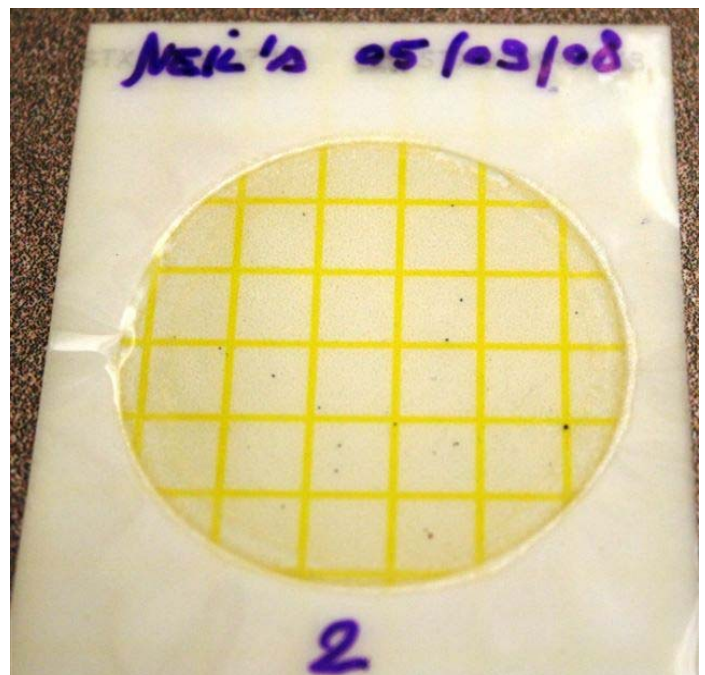
Week-1 test after start of Chrisal use



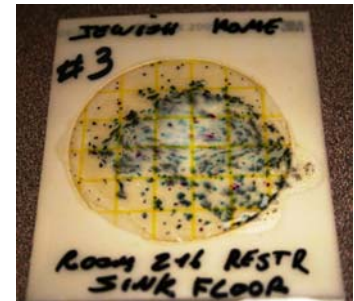
Week-2 testing



Week-3 testing



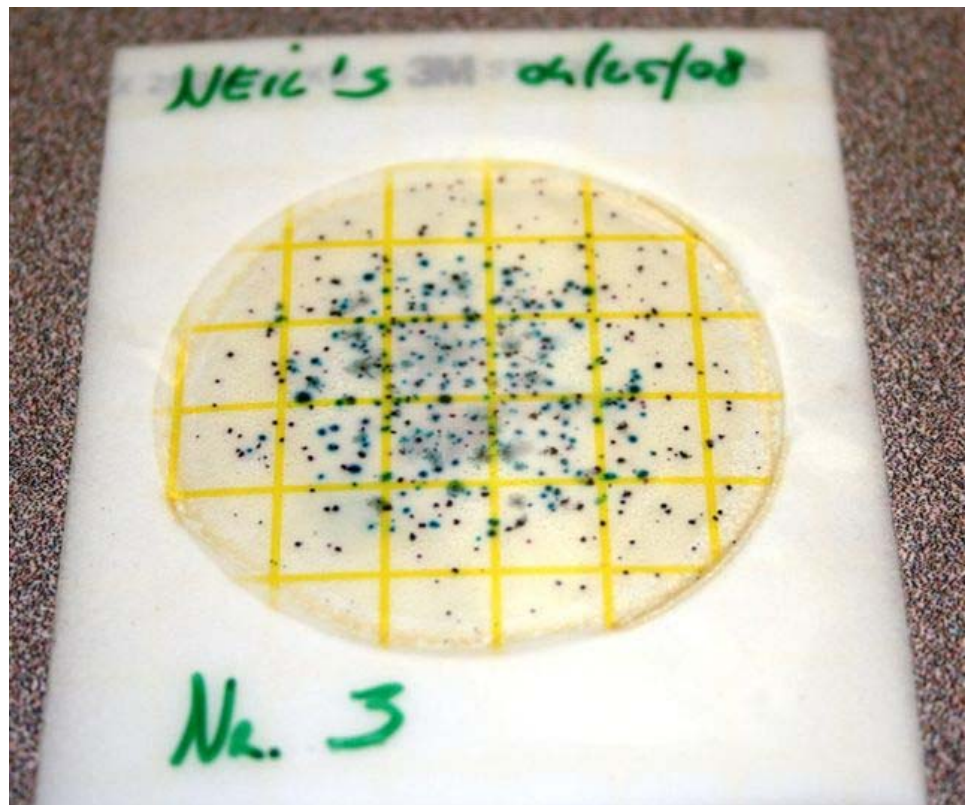
Progress of Chrisal PIP usage testing in the most heavily contaminated area:

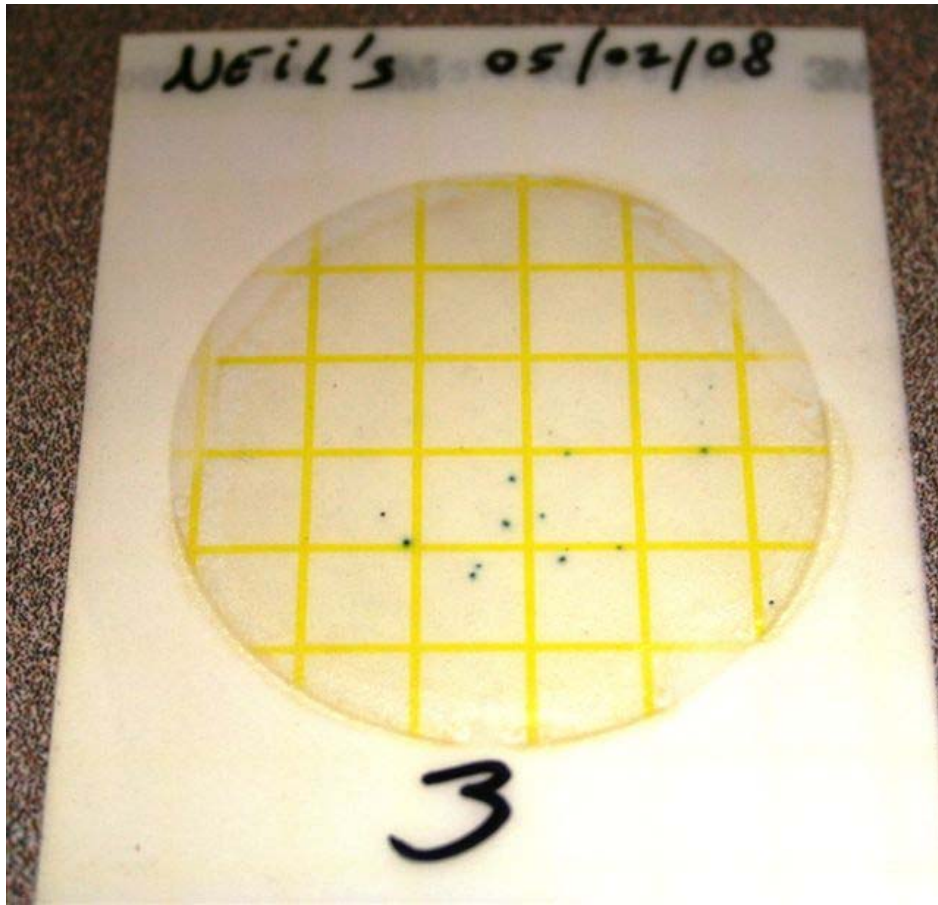


This room was the most contaminated starting point.

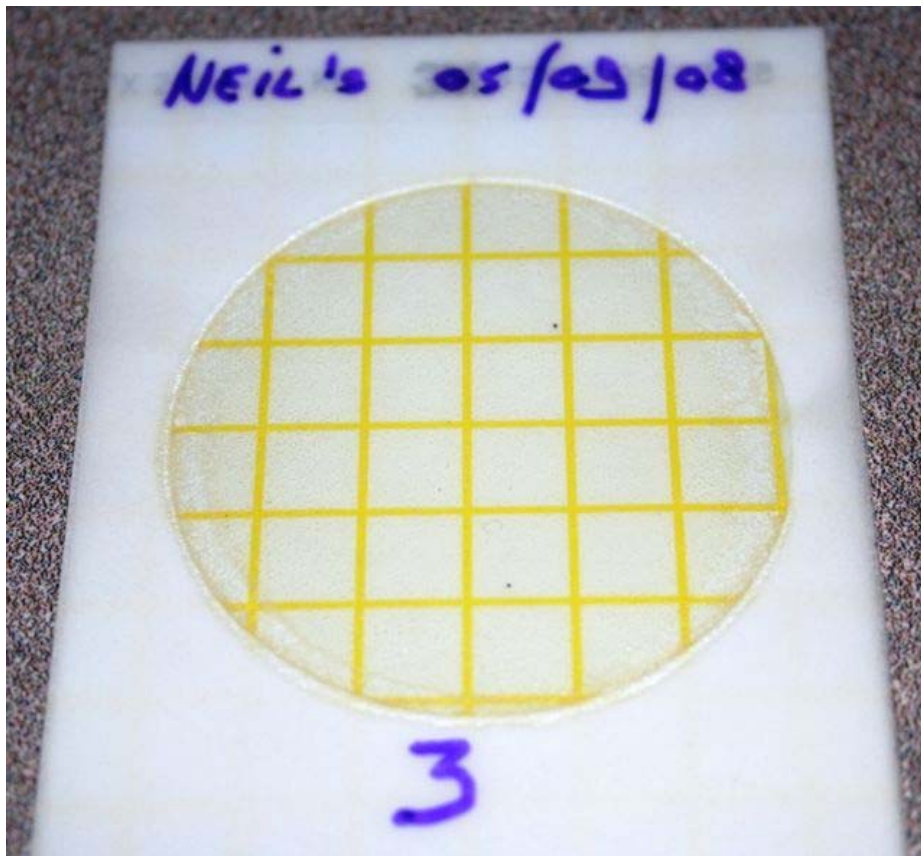
These slides were the pre-testing samples taken

Week-1
After one week of Chrisal PIP use the reduction in pathogens was significant





The further reduction in contamination can be seen in Week-2 above and then In Week-3 below of continued Chrisal PIP use

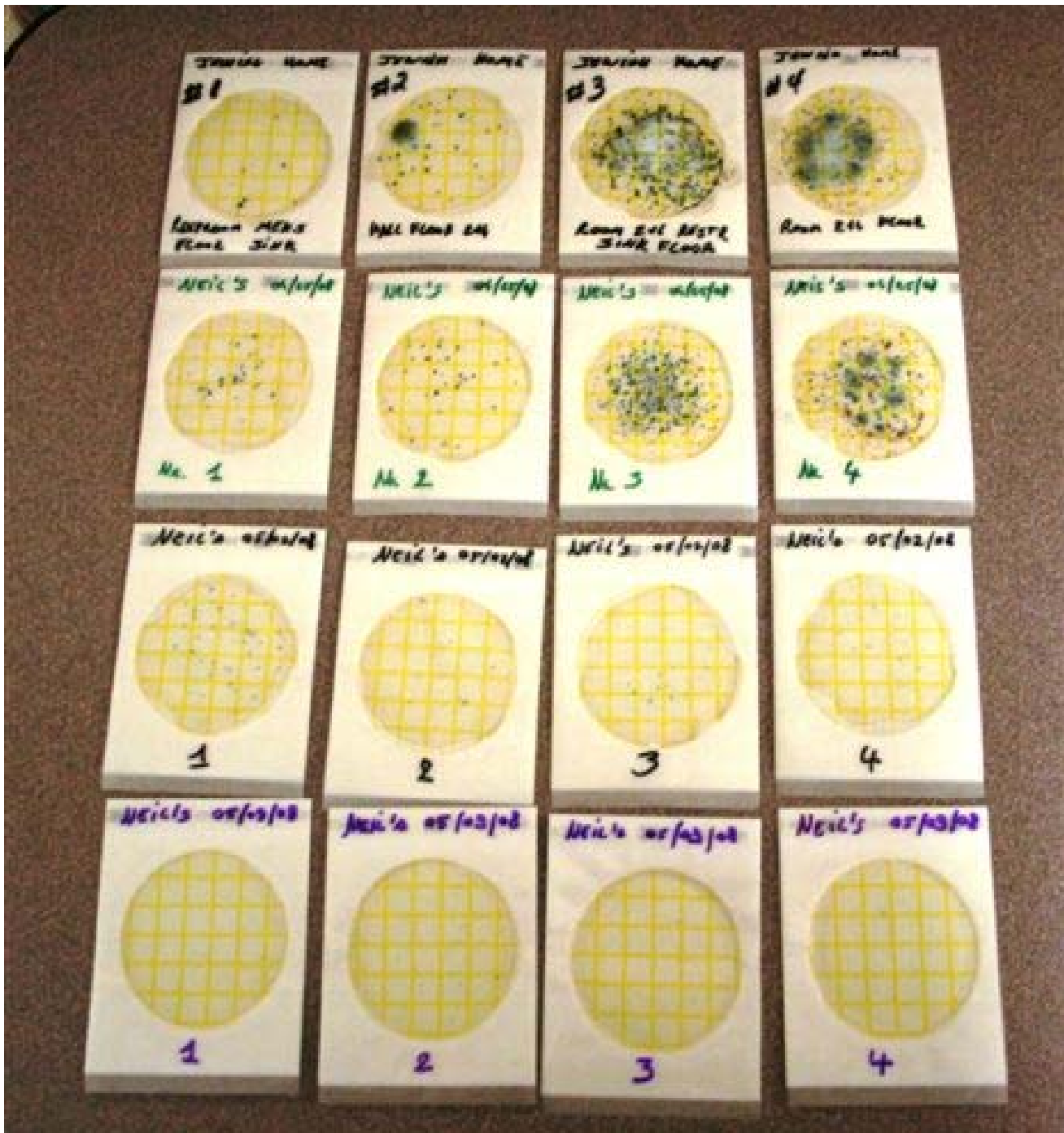


PATTERN OF RESULTS WITH CHRISAL PIP TESTING

As can be seen by the overall view of the first group of tests, the pre-testing cultures are in the top row to set the standard. The second row is the test results from after one week of using Chrisal PIP Healthcare – the 3rd row is week-2 and the 4th row is week-3.

Overall, the Chrisal products performed in line with the claimed performance. That the PIP (Probiotics-In-Progress) action of Chrisal would build control of the environment in all areas used over a short period of a few weeks. In support of this, the test results were fairly dramatic by the end of the second week and showed solid control by week-3.

This resulting control & reduction of pathogens has now continued for 3 months.



SUMMARY OF PHASE-1 TEST RESULTS FOR INFECTIOUS BACTERIA

In all locations that we used and tested the Chrisal PIP cleaning products, the results were all positive and greatly reduced or eliminated pathogens. In most cases the product provided fairly immediate positive results and in the rest of the cases, solid control of all areas was established by the end of the second week.

Once established in any area, Chrisal has continued to perform and provide protection for us without faltering. After the two week start up phase, without failure, Chrisal's performance has been exceptional now going into the 4th month.

NOTE - EXCEPTION THAT PROVED THE POINT

It is important to note that there was one incident during the testing period that we at first thought was a problem with Chrisal when there was a serious spike in Staphylococcus contamination by the bed in patient room 216.

Since room 216 was posted with a sign to only use Chrisal and no other products, when the contamination was discovered, we notified the Chrisal people and to confirm the situation, we spoke to the staff for that area and then discovered that there was a death in that room during the night shift and due to some body fluids spilled, the duty person thought disinfectants should be used instead of Chrisal.

The interesting point was that where Chrisal had been left in place, there was no contamination. However, only where standard disinfectants had been used was there a spike in contamination. This was a major point of confirmation of the effectiveness of the Chrisal probiotics action.

WHY DISINFECTANTS DO NOT PROVIDE ONGOING PROTECTION

As seemly smooth surfaces are actually hills and valleys on a microscopic level, over time, the indentations fill with bio-film produced by harmful bacteria in response to quorum sensing. These layers of bio-film protect these pathogens as well as viruses along with trapping dirt. Disinfectants burn only the top layer of both harmful and beneficial bacteria alike. In minutes after the disinfectant dries, what is then left is an open, uncontested landscape full of dead bacteria that is a food source for the opportunistic bacteria protected by the bio-film. That is why disinfectants are temporary and potentially dangerous solutions compared to Chrisal PIP products that provide control of environments with beneficial bacteria.

TEST & RESULTS – PHASE TWO

Due to the unexpected, but exceptional results of using the Chrisal PIP products in our initial testing, the use of Chrisal products was expanded to additional areas of the Hospital.

One interesting test of the PIP action was demonstrated with use on the kitchen floors where you can see in the photos that use of Chrisal actually lightened the grout back towards its original color. We understand this was due to the elimination of the bio-film Build-up that normally occurs between tiles that normally requires re-grouting.

THE CLEANING PROPERTIES OF CHRISAL

The main thrust of this summary report has first been the control of infectious bacteria and to what degree was Chrisal's ability to biologically control pathogens in all the test areas.

However, the base of Chrisal is that they are cleaning products, which also proved to provide exceptional results.

One of the important function points of the tested product line is that they are progressive in action. Unlike disinfectants and normal cleaners, Chrisal's PIP products keep working for at least 72 hours after each application. This was a claim that was not taken at face value at first until after several weeks had gone by in phase two testing in the kitchen area when it was seen that the grout in the kitchen floors had lightened.

It was then seen that each cleaning produced cleaner surfaces over time with each application. It was interesting that in using Chrisal, mops stay clean. The cleaning of any surface was immediate and excellent according to normal cleaning standards and better in most cases than other products. The only exception was some types of dried matter in a few cases that took a second application. However, ingrained stains and heavily traffic areas also kept getting lighter and lighter with each week's usage.

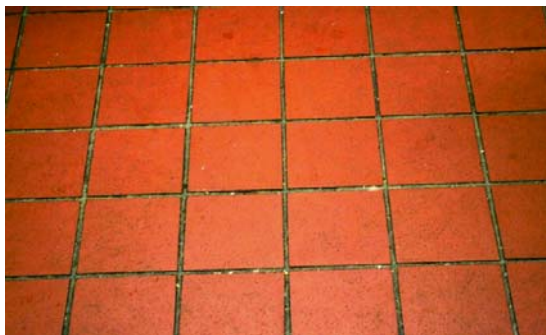
This supported the Chrisal PIP claims that the product both kept protecting against pathogens and kept providing cleaning action for some 72 hours after each application.



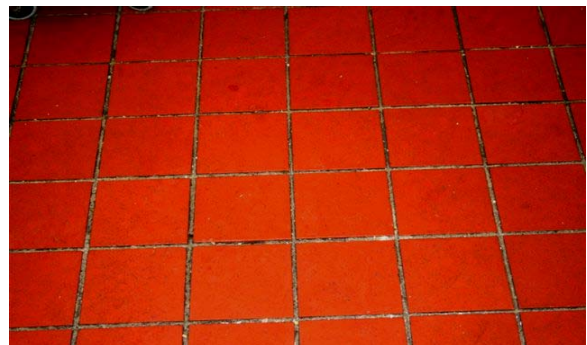
Pre-Chrisal MJHH Kitchen Floor



Grout in kitchen tiles starting to lighten with Chrisal use



Significant lighting of the tiles & grout after several weeks from black to gray



Lighting of the grout and tiles continues with PIP use.

CONCLUSIONS

In the three months since the Hospital started using Chrisal's PIP products, it has been seen that harmful bacteria has been reduced to levels that do not show up on most testing. Further, the PIP ongoing action has proved to keep protecting PIP cleaned surfaces between cleanings.

It should be noted that in addition to the obvious benefits of Chrisal for patient safety, the product line also serves as a major insurance policy for the hospital to reduce the risk of law suites as well as provide the best in patient safety.

In addition to the protection against pathogens, the Chrisal PIP product line has also proved to be exceptional cleaners. The three Chrisal PIP products used were the PIP Floor Cleaner, the PIP Universal (Interior) Cleaner and the PIP Sanitizer Cleaner for rest room areas and all have performed perfectly and have impressed everyone that has been part of the testing.

NOTE ABOUT PIP ALLERGY FREE SPRAY

The one Chrisal product that was not originally part of the testing protocol is the Chrisal PIP Allergy Free Spray.

This spray was not included as it is not normally considered a cleaning product, though it also does provide protection against harmful bacteria.

The PIP Allergy Free Spray is normally used on bedding and furniture where patients may spend time when out of bed. The spray has a major affect on reducing allergens and dust mites, which is a major health factor for patients with allergies and/or asthma.

The affects on all that have tested the PIP Allergy Free spray to date; including staff that properly tested the product was so effective that we started spraying the bed sheets with the product to further provide the significant healing effects realized by reducing the allergens that sap patient immune systems, including non-asthma/non-allergic patients.

The product also has a number of other applications to reduce contamination and allergens in ventilation systems and to provide protection from harmful bacteria in hard to reach areas, tubing and other situations.

Studies on the costs of infections found that post surgical wound infections more than double a patient's hospital costs (infections after surgery increases costs by **119%** on average, at teaching hospitals, and **101%** percent at a community hospitals. Urinary tract infections increase hospital costs by **47%** & **35%** respectively. The average ventilator-associated pneumonia infection adds **\$40,000** to hospital costs and *Staphylococcus aureus* infections are especially costly more than tripling the average hospital costs.

It is hoped that this report (and the future ones to come) will provide both an additional safety factor and an economical solution for our facilities.

Neil Caseiro, Director Environmental Services & Special Projects
Miami, July 25, 2008